UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/633,835	08/04/2003	Tedd E. Elich	9280.2	5061

20792 7590 10/13/2006

MYERS BIGEL SIBLEY & SAJOVEC
PO BOX 37428
RALEIGH, NC 27627

EXAMINER	
BASKAR, PADMAVATHI	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 10/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/633,835	ELICH ET AL.	
	Examiner	Art Unit	
	Padmavathi v. Baskar	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 August 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10,12,13 and 16-22* is/are pending in the application.

4a) Of the above claim(s) *4-7,9 and 16-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,8,10, 12 and 13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *6/15/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment filed on 8/9/06 is acknowledged.

Status of Claims

2. Claims 1-13 and 16-22 are pending in the application.

Claim 1 has been amended.

Claims 11, 14 and 15 are canceled.

Claims 1, 2, 3, 8, 10 12 and13 are under examination with respect to SEQ.ID.NO: 2.

Claims 4-7, 9 and 16-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a non elected inventions.

Information Disclosure Statement

3. Supplemental Information Disclosure Statement filed on 8/9/06 are acknowledged and a signed copy of each is attached to this Office action.

Claim Rejections - 35 USC 102 withdrawn

4. In view of amendment to the claim 1, the rejection under 35 U.S.C. 102(b) as being anticipated by Waldrop et al Biochemistry; 1994; *33*(34) pp 10249 - 10256;

Claim rejections 35 U.S.C. 112, second paragraph maintained

5. The rejection of claims 1, 2, 3, 8 and 10, 12, 13 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is maintained for claim 1 as being vague as set forth in the previous office action.

Claim I is vague in reciting, "having a functional biotin carboxylase (BC) domain" because it is unclear how an ACCase still comprise (i. e, having) a functional biotin carboxylase (BC) domain after having deleted biotin binding domain and carboxy transferase domain? It appears from the specification that isolated ACCase comprises biotin binding domain, carboxy transferase domain, and biotin carboxylase (BC) domain. Therefore, after having deleted biotin binding domain and deleted carboxy transferase domain, the ACCase should consist a biotin carboxylase (BC) only.

Applicants argue that the term" deleted" specifically disclosed in the specification and shows support that the term "deleted" has been used in other cited published Patents.

Applicant's arguments 8/9/06 have been fully considered but they are not deemed to be persuasive because the issue here is whether or not the term is used in the claims but claim is rejected as being vague and confusing as stated in the above paragraph.

New rejections based on the amendment

Claim Rejections - 35 USC 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -- -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 - 3 are drawn to a peptide comprising an Acetyl CoA carboxylase (ACCase) having a deleted biotin binding domain, having a deleted carboxy transferase domain, and having a functional biotin carboxylase domain wherein said peptide binds to soraphen, said carboxylase is Ustilago maydis carboxylase, wherein said peptide is a monomer (claim 10), wherein said peptide binds to soraphen(claim 12) and has a soraphen dissociation constant of from l0-^{7} to 10^{14} M.

7. Claims 1 -3 , 10 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Bailey et al Mol Gen Genet (1995) 249: 191-201(IDS 11/17/03):

Claims 1 - 3 are drawn to a peptide comprising an Acetyl CoA carboxylase (ACCase) having a deleted biotin binding domain, having a deleted carboxy transferase domain, and having a functional biotin carboxylase domain wherein said peptide binds to soraphen, said carboxylase is Ustilago maydis carboxylase, wherein said peptide is a monomer (claim 10), wherein said peptide binds to soraphen(claim 12) and has a soraphen dissociation constant of from l0-^{7} to 10^{14} M.

The art discloses the product, BC domain of *U.maydis* was amplified using 20mer oligonucleotides and the genomic DNA of *U.maydis* as a template, The deduced amino acid sequences of a single product in buffer obtained from amplification and subsequently cloned pUm1 in figure 2 indicates that it is a BC domain (see page 193, left column, first para) of *U.maydis* . The amino acid sequence covering BC domain of yeast in Figure 1 was also disclosed. Given that the deduced amino acid sequence of the encoded peptide, one would immediately envision the polypeptide in monomeric form. Further, although the reference does not teach that the peptide binds to soraphen, has a soraphen dissociation constant of from l0-^{7} to 10^{14} M, given that the peptide comprises the BC domain, given that it is isolated from the same source as instantly claimed peptide, the disclosed prior art reads on the claims 10 and 12 . The office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed peptide is functionally different than those taught by the prior art and to establish patentable differences. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.)

Further , given that the peptide comprises the BC domain, given that it is isolated from the same source *U.maydis*, the claimed peptide is anticipated because the peptide will inherently bind to soraphen and has a soraphen dissociation constant of from l0-^{7} to 10^{14} M. See Ex parte Novitski 26 USPQ 1389 (BPAI 1993).

8. Claims 1-2,10 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Schulte et al 1997 Proc. Natl. Acad. Sci. USA Vol. 94, pp. 3465-3470.

Claims have been disclosed supra.

Schulte et al disclose deduced amino acid sequences covering the BC domain of yeast ACCase in Figure 5. Although the reference does not teach that the peptide binds to soraphen, has a soraphen dissociation constant of from I0-^{7} to 10^{14} M, given that the peptide comprises the BC domain, given that it is isolated from the same source as instantly claimed peptide, the disclosed prior art reads on the claims 10 and 12 . The office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed peptide is functionally different than those taught by the prior art and to establish patentable differences. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.)

Given that the peptide comprises the BC domain, given that it is isolated from yeast, the claimed peptide is anticipated because the peptide will inherently bind to soraphen and has a soraphen dissociation constant of from I0-^{7} to 10^{14} M. See Ex parte Novitski 26 USPQ 1389 (BPAI 1993). Thus the prior art anticipated claims 1 , 2 , 10 and 12.

Rejection(s) under 35 U.S.C § 103

9. The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or *described as* set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person. having ordinary skill in the art to which said *subject matter* pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.,* 148 USPQ 459, that are applied for establishing a background for determining obviousness under 35 U.S.C. § 103(a) are summarized as follows:
1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or unobviousness.

10. Claims 1 -3 , 10 , 12 and 13 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Bailey or Schulte et al and each in view of Trubetskoy et al U.S.Patent 7,098,032

Claim 13 is drawn to a composition comprising: (a) an aqueous carrier solution; and (b) the peptide of claim I solubilized in said aqueous carrier solution; with said peptide included in said composition in an amount of from 0.001 nanograms to 20 milligrams per milliliter of aqueous carrier solution; said peptide having a soraphen dissociation constant in said composition and said composition having a pH of from 5 through 9.

The teachings of Bailey or Schulte et al as explained above teach a product in aqueous solution and do not disclose composition having a pH of from 5 through 9.

However, Trubetskoy et al teach that drug delivery exploits various physiological and intracellular PH gradients for the purpose of controlled release of drugs. Further , the art suggests the polymer's ability to retain(release) a bioactive substance (drug) in a physiologically tolerated pH range is 5.5-8 (see column 9, lines 39-41). Thus the art teaches physiologically tolerated composition's pH range is 5.5-8 and it was well known and conventionally practiced in the art at the time of the invention. For instance, Trubetskoy taught a variety of compositions that include peptides, lipids and liposomes at various pH ranges (see for example; column 8, lines 30-53) depending on the sensitivity of the drug. Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to maintain the product as taught by Bailey or Schulte in a composition comprising said peptide in aqueous carrier solution at physiologically tolerated pH range around 5-8 to produce the instant invention with a reasonable expectation of success. One of skill in the art would have

been motivated to produce the instant invention for the expected benefit of overcoming or avoiding the problem of pH associated drug delivery (see column 1,lines 63-65) as taught by Trubetskoy.

Claims 1 and 13 are prima *facie* obvious over the prior art of record.

Relevant Prior Art

11. The prior art made of record and not relied upon in any of the rejections is considered pertinent to Applicants' disclosure:

Vahlensieck et al U.S.Patent 5641,666:

Vahlensieck et al teach mutation at position 77 in yeast ACCase BC leads to drug/antibiotic resistance i.e., soraphen A resistant yeast (soraphen A drug resistant). Thus the art teaches the binding site for developing resistance is located in BC. Further, the art teaches methods of isolating a gene that encodes soraphen resistant biotin carboxylase enzyme (see abstract and columns 2-4 for example US 5641666). Thus the art identified the key component of biotin carboxylase domain that is involved in soraphen A drug resistance. The art suggests that this site can be used in assays to identify inhibitors of soraphen A resistant ACCase.

Kimura, Journal of Bacteriology, October 2000, Vol. 182, No. 19, p. 5462-5469:

Kimura et al teach *Myxococcus xanthus* biotin carboxylase subunits of acetyl coenzyme A (acetyl-CoA) carboxylases. The fragment contained two open reading frames (ORF1 and ORF2), designated the *accB* and *accA* genes, capable of encoding a 538-amino-acid protein of 58.1 kDa and a 573-amino-acid protein of 61.5 kDa, respectively. The protein (AccA) encoded by the *accA* gene was strikingly similar to biotin carboxylase subunits of acetyl-CoA and propionyl-CoA carboxylases and of pyruvate carboxylase. An *accA* disruption mutant showed a reduced growth rate and reduced acetyl-CoA carboxylase activity compared with the wild-type strain. Western blot

analysis indicated that the product of the *accA* gene was a biotinylated protein that was expressed during the exponential growth phase.

Levert et al, Biochemistry, 39 (14), 4122 -4128, 2000:

Levert teaches Biotin carboxylase from *Escherichia coli* catalyzes the ATP-dependent carboxylation of biotin and is one component of the multi enzyme complex acetyl-CoA carboxylase.

Remarks

12. No claims are allowed.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP ' 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

14. Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center, which receives transmissions 24 hours a day and 7 days a week. The transmission of such papers by facsimile must conform to the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The Right Fax number is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PMR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PMR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Padma Baskar Ph.D., whose telephone number is ((571) 272-0853. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 6.30 a.m. to 4.00 p.m. except First Friday of each bi-week.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Albert Navarro can be reached on (571) 272-0861. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Padm Baskar Ph.D.

SUSAN UNGAR, PH.D
PRIMARY EXAMINER